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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,319	07/31/2000	Arthur M. Krieg	C1039/7042	5464

7590 01/05/2004

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/630,319	KRIEG ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 42-130 is/are pending in the application.

4a) Of the above claim(s) 42-87,102 and 104-130 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 88-101 and 103 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8-03.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office action is in response to the communications filed 8-20-03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-20-03 has been entered.

Election/Restrictions

This application contains claims 42-87, 102, 104-130 drawn to inventions nonelected with traverse in paper filed 1-14-02. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

Claims 88-101 and 103 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement over the scope claimed, for the reasons of record set forth in the Office action mailed 2-24-03.

Applicant's arguments filed 8-20-03 have been fully considered but they are not persuasive. Applicants argue that a detailed description of CpG immunostimulatory

nucleic acids have been provided that are useful in treating immune deficiencies for treatment and prevention of bacterial infection is presented on pages on 15-17 of the instant specification, and methods for determining the stimulation index of a particular CpG DNA is also described in the instant specification, thereby enabling the full scope of the claimed invention. Contrary to Applicants' assertions, the listing of infectious bacteria, the listing of CpG containing oligonucleotides that induce cytokines including IL6 and IL12, and that demonstrate B cell and NK cell activation are not representative of the ability to prevent any bacterial infection in any subject. The immunostimulation or treatment of bacterial infections comprising the administration of CpG containing oligonucleotides is not predictive of the ability to prevent any bacterial infections in any subject. The specification and the references provided do not teach a correlation between CpG immunostimulation and the prevention of a representative number of bacterial infections in any subject.

Applicants argue that sufficient guidance has been provided in the instant disclosure of routes of administration and oligonucleotide types, as well as dosages. Contrary to applicants' assertions, the generic recitation of routes of administration utilized in the art for oligonucleotides is not enabling for the dosage required for any CpG containing oligonucleotide to prevent any bacterial infection in any subject. Applicant argues that the recent review article by Krieg enables the full scope of the claimed invention because it cites successful treatment of various infectious diseases. Treatment of mice challenged with Listeria monocytogenes and Fancisella tularensis using a particular CpG ODN using a particular dosing regimen is not representative of

the ability to prevent any bacterial infection in any subject comprising the administration by any means of any CpG containing ODN. It would require undue experimentation beyond that shown in the instant disclosure to determine the proper dosing regimen, CpG ODN sequence, and route of administration to prevent any bacterial infection using any CpG ODN in any subject. Enhanced protective responses under particular conditions upon administration of a particular CpG ODN are not representative of bacterial prevention in any subject using any CpG ODN.

Applicant admits that some CpG ODN's are more active than others. It is not argued that CpG ODN's promote an immune response. The ability to predict efficacy of a particular CpG ODN in preventing any bacterial infection in any organism requires undue experimentation because it is a highly unpredictable endeavor to determine the proper dosing and appropriate oligonucleotide sequence for preventing any bacterial infection in any subject comprising administration of a CpG ODN. Therefore, the instant enablement rejection is maintained.

Claims 88-101, 103 and 104 are rejected under the judicially created doctrine of double patenting over U. S. Patent Nos. 6,207,646, 6,194,388 and 6,239,116 for reasons of record set forth in the Office action mailed 2-24-03.

No arguments were made addressing these rejections.

Conclusion

This is an RCE of applicant's earlier Application No. 09/630,319. All claims are drawn to the same invention claimed in the earlier application and could have been

finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.**

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

JZ

December 12, 2003